



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815

21125 7590 08/16/2006

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,688	Applicant(s) ALTSHULER ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-24,26-34 and 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-17, 19-24,26-34 and 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>020206</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed June 16, 2006 have been fully considered but they are not persuasive.

The indicated allowability of claim 35 is withdrawn in view of the newly discovered reference(s) to Eckhouse. Eckhouse teaches the use of a gel with an index of refraction that is close to that of skin. This is relatively easy since the index of refraction of the skin is of the order of 1.4 in the visible and the near infrared. Rejections based on the newly cited reference(s) follow.

The indicated allowability of claim 36 is withdrawn in view of re-evaluation of the prior art and the Applicant's disclosure. The molecular weight is not discussed at all in the specification and thus raises the question as to its criticality to the method. The prior art also does not discuss molecular weight further implying it is not considered a critical factor to those of skill in the art.

Applicant's arguments regarding Neuberger are not persuasive. In teaching lower power levels (<10 mW) as an alternative to higher powers, Neuberger implicitly teaches that higher powers are known in the art. Regarding dosages, Neuberger, being a toothbrush, is used several times a day with the time chosen for each use inherently selecting a dosage.

Applicant's argument regarding photosensitizer definition is not persuasive. Stedmans Medical Dictionary defines photosensitization as - 1. Sensitization of the skin to light, usually due to the action of certain drugs, plants, or other substances. The use of Photosensitizers is pervasive in the art and such compounds are commonly referred to as dyes, drugs or compounds and a skilled artisan would select such a compound based on the properties required i.e. wavelength. The level of skill in the art regarding PDT and photosensitizers must be considered (claims 15, 23 and 24). It is proper to take into consideration not only the

Art Unit: 3739

teachings of the prior art, but also the level of ordinary skill in the art. In re Luck, 476 F.2d 650, 177 USPQ 523 (CCPA 1973). Specifically, those of ordinary skill in the art are presumed to have some knowledge of the art apart from what is expressly disclosed in the references. In re Jacoby, 309 F.2d 513, 135 USPQ 317 (CCPA 1962).

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The molecular weight including in claim 36 is not disclosed in the specification. The applicant is cautioned not to include any new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 16, 17, 20-22, 25-29, 40-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,056,548 to Neuberger et al. Neuberger et al. teach a laser toothbrush applicator and a method to use the toothbrush providing low power radiation in conjunction with an enhanced dental liquid or paste is described. The method provides a safe

Art Unit: 3739

hygienic dental treatment that can be practiced by anyone and enhances destruction of oral viruses and bacteria. The present invention teaches a method which will have a significant effect on the treatment of all types of oral diseases, inflammations, and infections. A pulsed diode laser as well as a continuous wave diode laser can be used with an enhanced dental liquid or paste for selective bio-stimulation within the oral cavity with little more effort than a conscientious person spends brushing their teeth (Col. 3, lines 12-24). The power of the device is disclosed as less than 10 mW (Col. 4, line 16) with treatment times of 1-3 minutes at a wavelength of 904 nanometers (Col. 1, lines 37-41). Teach explicitly that this power is lower than thought to be effective, Neuberger implicitly teaches the use of power levels above 10 mW. The device may also use photosensitizers (drug) and the wavelength is selected based on the specific photosensitizer (Col. 1, lines 60-67) with wavelengths of 670, 780 and 820 nanometers specifically disclosed. Lacking any means for restricting the radiation, the radiation would reach all soft tissue of the oral cavity including facial tissue and the red wavelengths are known to penetrate well. The brushing of teeth is typically done twice a day, thus providing multiple treatments. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Claims 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,699,040 to Hahn et al. in view of U.S. Patent 5,620,478 to Eckhouse. Hahn et al. teach a method for radiating within an oral cavity (Fig. 2) using a coupling material to maximize the transference of the radiation to tissue (Col. 15, lines 15-25). The material may be a liquid or a gel and may have fluorescent properties (Col. 3, line 5). Any liquid or gel has some

Art Unit: 3739

penetrating ability. Hahn et al. do not disclose a specific index of refraction. Eckhouse teaches the use of a gel with an index of refraction that is close to that of skin. This is relatively easy since the index of refraction of the skin is of the order of 1.4 in the visible and the near infrared (Col. 13, lines 36-42). It would have been obvious to one skilled in the art to choose the index of refraction of 1.4 as taught by Eckhouse in the method of Hahn et al. as both seek to maximize coupling of the irradiation to tissue.

Regarding claim 34, Hahn et al. teach the use of infrared wavelengths (Col. 14, line 34).

Regarding claim 36, the molecular weight is not disclosed as being critical to the method or of yielding any unexpected result and is therefore considered an obvious design choice of a skilled artisan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Neuberger et al. are discussed above, but do not teach lower wavelengths. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides profilaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Neuberger et al. as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,135,774 to Hack et al. Neuberger et al. are discussed above, but do not teach the use of diagnostic signals. Hack et al. teach a device for detecting fluorescence from teeth that may be used as a measure of whiteness. One of the disclosed uses of Neuberger et al. is for tooth whitening, so it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the detector as taught by Hack et al. in the method of Neuberger et al. as feedback regarding a whitening procedure.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 20 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Neuberger et al. are discussed above, but do not teach wavelengths below 670 nanometers. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory

Art Unit: 3739

action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides profilaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Neuberger et al. as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,623,513 to Biel. Neuberger et al. are discussed above, but do not teach the systemic introduction of the photosensitizer. Biel teaches photosensitizers for Photodynamic therapy introduced by intravenous injection (col. 1, line 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the photosensitizer as taught by Biel in the method of Neuberger et al. as an alternative means to provide the sensitizer at the treatment site. Such injection is well known in the art.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 40 above, and further in view of U.S. Patent 6,623,513 to Biel. Neuberger et al. are discussed above, but do not teach the systemic introduction of the photosensitizer. Biel teaches photosensitizers for Photodynamic therapy introduced by intravenous injection (col. 1, line 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the photosensitizer as taught by Biel in the method of Neuberger et al. as an alternative means to provide the sensitizer at the treatment site. Such injection is well known in the art.

Art Unit: 3739

Allowable Subject Matter

Claim 18 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Henry M. Johnson, III
Patent Examiner
Art Unit 3739